

# FACTSHEET Medical Devices

## What is a medical device?



Breast implants are high-risk medical devices

A medical device is a product used to prevent, diagnose, or cure a disease or condition. Whereas a pharmaceutical operates chemically within the body, a medical device has a mechanical function.

Such devices are classified under different risk categories. Low-risk devices include contact lenses and plasters. Pacemakers and hip implants belong to the high-risk group.

The size of a medical device can also vary considerably, from a syringe needle to a mounted X-ray machine.

## Who checks whether they are safe?

As high-risk medical devices' role is to sustain human life – with some of them meant to be implanted in a patient's body – it is crucial they are properly assessed before being available on the market.

Currently, pre-market assessment is performed across the EU by approximately 80 'notified bodies'. These are mostly private companies chosen by medical device manufacturers - which means they can select the least strict. These notified bodies grant the 'CE' marking we see on many EU products – but, contrary to popular belief, this does not mean the product is safe.

## What about the breast and hip implants scandals?

If not of high quality, medical devices can become harmful. The lax nature of many safety controls have been tragically demonstrated by incidents which made major headlines.

In 2012, thousands of patients with PIP manufactured breast implants and separately those with faulty hip prostheses were victims of such lax oversight. Aside from stoking consumers' mistrust of the medical devices industry, such situations disrupted their daily lives.

The benefit a medical device gives a patient must outweigh the foreseeable risks

<sup>1</sup> Watch our five EU consumer testimonials: <http://bit.ly/1rUyZzq>



## 🗨️ What about the breast and hip implants scandals?

Medical devices are currently regulated by three different laws. The review of the medical devices Directive was launched in 2012 to update the legislation and fill regulatory gaps.

In early 2014, the European Parliament endorsed some changes which will certainly improve the situation.

Before having the device fitted, consumers will receive an implant card detailing the potential adverse effects. Once the device hit the market, monitoring will be enhanced thanks to easier defect report by consumers and better data collection.

## 🗨️ What does BEUC support?

Despite bringing about some improvements for consumers, the new legislation still needs bettering. As regards pre-market assessment of medical devices, BEUC has been calling for independent, publicly funded controls and more clinical data to prove the devices are safe and effective.

Clinical experts should be in charge, not non-experts who merely check if the device works - for instance whether a hip implant moves correctly.

The legislation as is will still not inspire a robust EU approval and monitoring system. Doing so is key in ensuring a more coherent, risk-based classification system and better market surveillance.

Manufacturer liability still needs to be increased by instituting insurance and their upping traceability. Consumers have the rights to receive more and better information on medical devices. If problems occur, consumers should receive proper follow-up and commensurate compensation for the harm suffered.

Such conditions are essential for guaranteeing European consumers with timely access to innovative treatments without compromising their safety.

As the new regulation stands today, consumers will still be guinea pigs.

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<sup>2</sup> ['BEUC position on the Regulations on medical devices'](#), March 2013